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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.            | CONFIRMATION NO.       |
|---|-------------|----------------------|--------------------------------|------------------------|
| 10/646,391  | 08/21/2003  | Martin Gleave        | UBC.P-035                      | 9734                   |
| 57381 7590 12/20/2006<br>Marina Larson & Associates, LLC<br>P.O. BOX 4928<br>DILLON, CO 80435 |             |                      | EXAMINER<br>BOWMAN, AMY HUDSON |                        |
|   |             |                      | ART UNIT<br>1635               | PAPER NUMBER           |
|   |             |                      | MAIL DATE<br>12/20/2006        | DELIVERY MODE<br>PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |                 |               |  |
|---|-----------------|---------------|--|
| <b>Advisory Action</b><br><b>Before the Filing of an Appeal Brief</b> | Application No. | Applicant(s)  |  |
|   | 10/646,391      | GLEAVE ET AL. |  |
|   | Examiner        | Art Unit      |  |
|   | Amy H. Bowman   | 1635          |  |

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 20 November 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal.

Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☒ Applicant's reply has overcome the following rejection(s): rejection of claim 14 under 35 U.S.C 112, first paragraph.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_  
Claim(s) objected to: \_\_\_\_\_  
Claim(s) rejected: \_\_\_\_\_  
Claim(s) withdrawn from consideration: \_\_\_\_\_

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
13. ☐ Other: \_\_\_\_\_

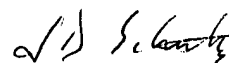
Continuation of 11. does NOT place the application in condition for allowance because: It is noted that a petition regarding the restriction requirement was filed on 10/3/06 and is pending a decision. Therefore, applicant has not cancelled the non-elected subject matter of the pending claims.

Applicant's arguments do not overcome the pending rejection of claim 1 under 35 U.S.C. 112, first paragraph. As explained in the office actions mailed on 4/14/06 and 9/18/06, one of ordinary skill in the art would not recognize that applicant was in possession of such a large scope of therapeutic agents, as instantly recited. Upon further consideration, the description regarding antisense oligonucleotides and RNAi inhibitors is sufficient to describe oligonucleotides, as recited in claim 14.

With regards to claim 1, applicant argues that applicants have no control over inhibitors that have not yet been described in the art. However, the test for written description is possession and applicant clearly is not in possession of any therapeutic agent that is effective to reduce the amount of clusterin in melanoma cells by disclosing antisense oligonucleotides and RNAi inhibitors. The claim embraces a multitude of inhibitors such as small molecule inhibitors, antibodies, miRNAs, ribozymes, aptamers, as well as any other inhibitory agent. It is noted that it is improper for applicant to argue an unpublished board decision and such arguments have not been considered.

Applicant argues *In re Fuetterer*, which was responded to by the examiner in the office action mailed on 9/18/06. The examiner is not requiring for applicant to discover which possible therapeutic agents will function properly in the method, but rather is requiring a description of an adequate number of species of therapeutic agents to be used by the method that is commensurate with the scope of the instant claim so that one of ordinary skill in the art would recognize that applicant was in possession of the claimed invention.

Claims 2-10 and 14 would be allowable if the non-elected subject matter of claims 3, 6, and 9 was cancelled. Additionally, it is noted that if the non-elected subject matter were cancelled, claims 6 and 7, as well as claims 9 and 10, would be substantial duplicates.



JAMES SCHULTZ, PH.D.

Supervisory PRIMARY EXAMINER